## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: Christian FRISCH et al.

Serial No.: Unassigned

Art Unit: Unassigned

(based on Serial No. 09/795,872 filed 2/28/01)

Filed: September 16, 2003

Examiner: Unassigned

For:

GENERATION OF SPECIFIC BINDING PARTNERS BINDING TO

(POLY)PEPTIDES ENCODED BY GENOMIC DNA FRAGMENTS OR ESTs

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56 and 37 CFR §1.97

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08A is a listing of documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. §1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* prior art reference against the claims of the present application.

The documents submitted herewith on Form PTO/SB/08A, lists the documents cited by or submitted to the Patent Office in parent application Serial No. 09/795,872 filed February 28, 2001. The relevance of these prior art documents is explained in the parent application.

As provided in 37 C.F.R. §1.98(d), copies of the documents are not being provided since they were previously cited by or submitted to the Patent Office in parent application Serial No. 09/795,872 filed February 28, 2001.

The instant Information Disclosure Statement is being filed within three months of the filing date under 37 CFR §1.97(b)(1), therefore, no fee is required in connection with its filing. However, the Commissioner is hereby authorized to charge any deficiency or to credit any overpayment to Deposit Account No. 08-1641

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-SB/08A be returned in accordance with M.P.E.P. §609.

Respectfully submitted,

Date Date 16, 7003

Colin G. Sandercock Reg. No. 31.298

10,244

Customer ID No. 26633

HELLER EHRMAN WHITE & McAULIFFE LLP

1666 K Street, N.W., Suite 300

Washington, DC 20006

Telephone:

(202) 912-2000

Facsimile:

(202) 912-2020

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute	e for form 1449A/PTC	)		Complete if Known			
				Application Number	Unassigned		
INFO	RMATION	DIS	CLOSURE	Filing Date	September 16, 2003		
STAT	TEMENT B	Y A	PPLICANT	First Named Inventor	Christian FRISCH et al.	_	
				Group Art Unit	Unassigned		
	(use as many she	ets as	necessary)	Examiner Name	Unassigned		
Sheet	1	of	4	Attorney Docket Number	37629-0079		

				U.S. PATENT DOCUM	MENTS	
		U.S. Par	tent Document	Name of Patentee or Applicant	Date of Publication of	Pages, Columns, Lines, Where Relevant
Examiner Initials *	Cite No.1	Number	Kind Code <sup>2</sup> (if known)	of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear
	A01	5,895,6	51	Simons et al.	4/1999	
	A02	5,814,4	77	Williams et al.	9/1998	
	A03	5,989,5	54	Knuth et al.	11/1999	
,,,,,						

FOREIGN PATENT DOCUMENTS										
Examiner	Cite	For	eign Patent Doc	ument	Name of Patentee or	Date of Publication	Pages, Columns, Lines,			
Initials*	No.1	Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> ( <i>if known</i> )	Applicant of Cited Document	of Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>		
	A04	wo	98/30684			7/16/1998				

Examiner	Date
Signature	Considered

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>8</sup> Applicant is to place a check mark hee if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO Complet if Known Application Number Unassigned INFORMATION DISCLOSURE Filing Date September 16, 2003 STATEMENT BY APPLICANT First Named Inventor Christian FRISCH et al. Group Art Unit Unassigned (use as many sheets as necessary) **Examiner Name** Unassigned Sheet of 37629-0079 Attorney Docket Number

ļ		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A05	GUAN, C. et al., "Vectors that facilitate the expression and purification of foreign peptides in scherichia coli by fusion to maltosebinding protein", Gene, 1988, Vol. 67, pp. 21-30	
	A06	MAINA, C.V. et al., "An Escherichia coli vector to express and purify foreign proteins by fusion to and separation from maltosebinding protein", Gene, 1988, Vol. 74, pp. 367-373	
- · -	A07	RUDOLPH, R. et al., "In vitro folding of inclusion body proteins", FASEB J., 1996, Vol. 10, pp. 49-56	
!	A08	MARCZINOVITS, I. Et al., "An alternative purification protocol for producing hepatitis B virus X antigen on a preparative scale in Escherichia coli", J. Biotechnology, 1997, Vol. 56, pp. 81-88	
	A09	NANDI, A. et al., "Expression of the Extracellular Domain of the Human Heat-Stable Enterotoxin Receptor in Escherichia coli and Generation of Neutralizing Antibodies", Protein Expression and Purification, 1996, Vol. 8, pp. 151-159	
	A10	VAUGHAN, T.J., et al., "Human Antibodies with Sub-nanomolar Affinities Isolated from a large Non-immunized Phage Display Library", Nature Biotech., 1996, Vol. 14, pp. 309-314	
	A11	C. KREBBER et al., "Selectively-infective phage (SIP): A mechanistic dissection of a novel in vivo selection for protein-ligand interactions", <u>J. Mol. Biol.</u> , 1997, Vol. 268, pp. 607-618	
	A12	L. PERSIC et al., "Single-chain variable fragments selected on the 57-76 p21 Ras neutralizing epitope from phage antibody libraries recognize the parental protein", <u>FEBS</u> <u>Letters</u> , 1999, Vol. 443, pp. 112-116	
	A13	Y. HITOMI et al., 'High efficiency prokaryotic expression and purification of a portion of the Hepatitis C core protein and analysis of the immune response to recombinant protein in BALB/c mice", Viral Immunology, 1995, Vol. 8, pp. 109-119	_
	A14	G. HAGENDORFF et al., "A monoclonal antibody generated against a recombinant peptide fragment of the B3 domain of carcinoembryonic antigen reacts with intact carcinoembryonic antigen", <u>Biochemica et Biophysica Acta</u> , 1995, Vo. 1260, pp. 259-268	

Examiner	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute f	or form 1449A/PTC	)		Complete if Known		
INICA	ORA A TION	nie	CLOCUDE	Application Number	Unassigned	
		_	CLOSURE	Filing Date	September 16, 2003	
SIAI	EWENI B	YA	PPLICANT	First Named Inventor	Christian FRISCH et al.	
				Group Art Unit	Unassigned	
(	use as many she	ets as	necessary)	Examiner Name	Unassigned	
Sheet	3	of	4	Attorney Docket Number	37629-0079	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	A15	H. TAKEMURA et al., "Cloning and expression of human defensin HNP-1 genomic DNA in Escherichia coli", <u>Journal of Microbiological Methods</u> , 1996, Vol. 25, 287-293	
	A16	R. RUDOLPH and H. LILIE, "In vitro folding of inclusion body proteins", <u>The FASEB</u> <u>Journal</u> , 1996, Vol. 10, pp. 49-56	
	A17	JEAN-MICHEL BETTON et al., "Folding of a Mutant Maltose-binding Protein of Escherichia coli Which Forms Inclusion Bodies", The Journal of Biological Chemistry, April 5, 1996, pp. 8046-8052, Vol. 271, No. 14, The American Society for Biochemistry and Molecular Biology, Inc.	
	A18	DEB K. CHATTERJEE et al., "Cloning and overexpression of the gene encoding bacteriophage T5 DNA polymerase", Gene, 1991, pp. 13-19, Vol. 97, Elsevier Science Publishers	
	A19	GLEN A. COBURN et al., "Overexpression, Purification, and Properties of Escherichia coli Ribonuclease II", The Journal of Biological Chemistry, January 12, 1996, pp. 1048-1053, Vol. 271, No.2, The American Society for Biochemistry and Molecular Biology, Inc.	
	A20	NIEK DEKKER et al., "In vitro folding of Escherichia coli outer-membrane phospholipase A", Eur. J. Biochem., 1995, pp. 214-219, Vol. 232, FEBS	
	A21	ALAN I. DERMAN et al., "Escherichia coli Alkaline Phosphatase Localized to the Cytoplasm Slowly Acquires Enzymatic Activity in Cells Whose Growth Has Been Suspended: a Caution for Gene Fusion Studies", Journal of Bacteriology, July 1995, pp. 3764-3770, Vol. 177, No. 13, American Society for Microbiology	
	A22	JAN-OLOV HÖÖG et al., "Nucleotide sequence of the thioredoxin gene from Escherichia coli", Bioscience Reports, 1984, pp. 917-923, Vol. 4, The Biochemical Society, Great Britain	
	A23	ROBERT KUHELJ et al., "The preparation of catalytically active human cathepsin B from its precursor expressed in Escherichia coli in the form of inclusion bodies", Eur. J. Biochem., 1995, pp. 533-539, Vol. 229, FEBS	
	A24	URSULA RINAS et al., "Overexpression of Bacterial Hemoglobin Causes Incorporation of Pre-β-Lactamase into Cytoplasmic Inclusion Bodies", Appl. Environ. Microbiol., February 1993, pp. 561-566, Vol. 59, No. 2, American Society for Microbiology	

1	Examiner	Date	
-	Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute	e for form 1449A	/PTO		Complet if Known		
INICO	DAAATIC	NI DIC	CLOCUDE	Application Number	Unassigned	
			CLOSURE	Filing Date	September 16, 2003	
STATEMENT BY APPLICANT				First Named Inventor	Christian FRISCH et al.	
				Group Art Unit	Unassigned	
	(use as many	sheets as	necessary)	Examiner Name	Unassigned	
Sheet	4	of	4	Attorney Docket Number	37629-0079	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
	A25	KOEN VANDENBROECK et al., "Refolding and single-step purification of porcine interferon-y from Escherichia coli inclusion bodies Conditions for reconstitution of dimeric IFN-y", Eur.J.Biochem., 1993, pp. 481-486, Vol. 215, FEBS	
	A26	S. MAKRIDES, "Strategies for Achieving High-Level Expression of Genes in Escherichia Coli", Microbiological Review (1996) 512-538.	
!	A27	C. SCHEIN, "Solubility as a function of protein structure and solvent components", Bio/Technology vol. 8, (1990) 308-317	
	A28	D. WILKINSON et al., "Predicting the solubility of recombinant proteins in escherichia coli", Bio/Technology vol. 9 (1991) 443-448	
			ļ

	 		 	 $\overline{}$
Examiner	Date	<b>\</b>		1
Signature	Considered	ĺ		

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.